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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,014	03/01/2002	Henrik Hansen	12013/59301	2646

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KENYON & KENYON
1500 K STREET, N.W., SUITE 700
WASHINGTON, DC 20005

EXAMINER

TSOY, ELENA

ART UNIT PAPER NUMBER

1762

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,014	HANSEN ET AL.	
	Examiner	Art Unit	
	Elena Tsoy	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/15/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-29 is/are pending in the application.
- 4a) Of the above claim(s) 20-24 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18, 19 and 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 15, 2004 has been entered.

Response to Amendment

Amendment filed on November 15, 2004 has been entered. Claims 1-16, 18-29 are pending in the application. Claims 20-24 and 29 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 12, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201).

Vickery discloses a method of coating implant pellets for the delivery of therapeutic (See Abstract) comprising: placing spherical inert cores into a rotatable drum; tumbling the pellets by rotating the drum (obviously about a longitudinal axis of the drum); spraying a therapeutic in a

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solvent carrier over the tumbling cores (See column 14, lines 3-14); and removing the solvent using hot air (drying)(See column 9, lines 10-13). The pan bed temperature is set at 37 °C (i.e. of hot air is about of the same temperature) (See column 14, lines 10-11).

It is the Examiner's position that a spherical inert pellet is a medical implant as claimed because according to Applicants, "medical implants" may be used for numerous medicinal purposes including the delivery of therapeutic (See specification, page 1, lines 10-14).

Vickery fails to teach that the therapeutic is sprayed by moving it through a channel positioned in the drum and containing a plurality of orifices (Claim 1); the drum has a plurality of orifices in the wall (Claim 12).

Lucke teaches that coating cores in rotary drums containing a plurality of orifices 51 in the wall, where a pharmaceutical coating material is applied (See column 4, lines 21-22) by moving the coating materials through a carrier (channel) 54 positioned in the drum and having a plurality of spraying nozzles (orifices) 53, spraying the coating materials through the nozzles 53 (See Fig. 4; column 7, lines 30-38) and the applied coating is dried by blowing a gas, allows to achieve high quality of coated cores (See column 4, lines 34-35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated cores of Vickery using a rotary drum of Lucke containing a plurality of orifices, where a pharmaceutical coating material is applied by moving the coating materials through a carrier positioned in the drum and having a plurality of spraying nozzles, and spraying the coating materials through the nozzles, and the applied coating is dried by blowing a gas with the expectation of providing the desired high quality of coated cores, as taught by Lucke.

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3. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201), further in view of Yalkowsky (US 4,489,026).

Vickery in view of Lucke is applied here for the same reasons as above. Vickery in view of Lucke fails to teach that inert gas is used instead of air (Claim 3).

Yalkowsky teaches that while coating tablets in a rotating tumbler pan (See column 3, lines 65-66), inert gas can be used instead of air if desired (See column 4, lines 19-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used inert gas instead of air in Vickery in view of Lucke with the expectation of providing the desired high quality coated cores, Yalkowsky teaches that while coating tablets in a rotating tumbler pan, inert gas can be used instead of air if desired.

4. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201), further in view of Forster (US 4,581,242).

Vickery in view of Lucke is applied here for the same reasons as above. Vickery in view of Lucke fails to teach that implants are suspended above an internal surface of the drum.

Forster teaches blowing air or gas up through the bed of objects in a side vented coating pan (i.e. having a plurality of orifices in the wall as claimed) allows drying the objects at all levels (i.e. suspending the medical implants) provides defect-free coatings as they are held aloft (See column 1, lines 18-30, 42-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified a method of Vickery in view of Lucke to blow air up through the articles in the coating pan to suspend the medical implants with the expectation of providing the desired defect-free coatings as they are held aloft, as taught by Forster.

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5. Claims 5, 6, 8, 14-16, 18, 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iguchi et al (US 5,756,553) in view of Forster (US 4,581,242) and Schwartz et al (US 6,607,598).

Iguchi et al disclose a method of coating a medical implant with drug using rotary drum (See column 5, lines 37-42, 56-58). Multilayer coating may be applied to achieve a desirable amount of the drug in the coating (See column 6, lines 2-8).

Iguchi et al fails to teach that the drum and containing a plurality of orifices, and the medical implant has a masking material on at least one surface (Claim 5).

Forster teaches blowing air or gas up through the bed of objects in a side vented coating pan (i.e. having a plurality of orifices in the wall as claimed) allows drying the objects at all levels (i.e. suspending the medical implants) provides defect-free coatings as they are held aloft (See column 1, lines 18-30, 42-50). It is well known in the art that a coating pan rotates about an axis.

It is well known in the art to use masking techniques for partial coating of medical implants to result in coating of predetermined segments, as evidenced by Schwartz et al (See column 11, line 67; column 12, lines 1-2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used side vented rotary pan for coating a medical implant in Iguchi et al to blow air up through the articles to suspend the medical implant with the expectation of providing the desired defect-free coatings, as taught by Forster.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have masked portions of a medical implant before pan coating in Iguchi et al with

the expectation of providing the desired coating of predetermined segments of the medical implant, as well known in the art.

As to claim 6, Claim 6 is rejected because collection of any fluid inherently requires a reservoir.

As to claims 15, 26, Iguchi et al in view of Forster fail to teach that gas is an inert gas.

It is well known in the art that inert gas should be used in case a bioactive coating is sensitive to air.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used inert gas in Iguchi et al in view of Forster with the expectation of providing the desired high quality bioactive coating if a bioactive coating is sensitive to air.

As to claims 16, 28, blowing of air or gas does not continue indefinitely and thus is “periodic”.

As to claims 18, 25, Forster further teaches that coating can be sprayed through a nozzle 12 (See Fig. 4).

6. Claims 7, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201), further in view of Dunajtschik (US 4,586,457).

Vickery in view of Lucke is applied here for the same reasons as above. Vickery in view of Lucke fails to teach that air is re-circulated (Claims 7, 9).

Dunajtschik teaches that it is possible in principle to completely seal the inner space of the coating drum 2 against the atmosphere, so that either directly or within the surrounding housing the process can run with recirculated air (See column 7, lines 14-26).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have completely sealed the inner space of the coating drum in Vickery in view of Lucke against the atmosphere, so that either directly or within the surrounding housing the process can run with recirculated air with the expectation of providing the desired isolation of operation, as taught by Dunajtschik.

7. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201), further in view of Fernandez et al (US 3,696,188).

Vickery in view of Lucke is applied here for the same reasons as above. Vickery in view of Lucke fails to teach that cores coated with a first and a second bioactive coating layers.

Fernandez et al teach that inert cores can be coated with multiple bioactive coating layers depending on intended use of a final product (See column 3, lines 5-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated inert cores in Vickery in view of Lucke with multiple bioactive coating layers depending on intended use of a final product, as taught by Fernandez et al.

Response to Arguments

8. Applicant's arguments with respect to claims 1-16, 18, 19, 25-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elena Tsoy whose telephone number is (571) 272-1429. The examiner can normally be reached on Mo-Thur. 9:00-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive Beck can be reached on (571) 272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elena Tsoy
Primary Examiner
Art Unit 1762

ELENA TSOY
PRIMARY EXAMINER

ETSOY

December 1, 2004